SM

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,488	12/10/2003	Yaron Ilan	Enz-64(D3)	7675

7590 05/19/2004

EXAMINER
LE, EMILY M

ART UNIT	PAPER NUMBER
1648	

Ronald C. Fedus, Esq.
Enzo Therapeutics, Inc.
c/o Enzo Biochem, Inc.
527 Madison Avenue (9th Floor)
New York, NY 10022-4304

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/733,488	ILAN ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-62* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, drawn to a process of treating a disease with the administration of a mammalian intermediary metabolite, classified in class 435, subclass 262.

II. Claims 12-24, drawn to a process of treating a disease with the administration of a reagent, classified in class 435, subclass 262.

III. Claims 25-36, drawn to an ex-vivo process of treating a disease with the administration of a mammalian intermediary metabolite, classified in class 435, subclass 267.

IV. Claims 37-49, drawn to an ex-vivo process of treating a disease with the administration of a reagent, classified in class 435, subclass 267.

V. Claims 50-62, drawn to a process of treating a disease with the administration of a mammalian metabolite, classified in class 435, subclass 262.

The inventions are distinct, each from the other because of the following reasons:

2. The inventions of Groups I-II and V are directed to different methods requiring the different specific compounds. The invention of Group I requires the use of intermediary metabolites. The invention of Group II requires the use of reagents. The invention of Group III requires the use of metabolites. Intermediary metabolites, reagents, and metabolites are expected to differ from one another structurally and

biologically. The activities of an intermediary metabolite would not be the same as those for a reagent or a non-intermediary metabolite. Therefore, because of the compound that is employed in each group, the inventions of each group are patentably distinct from one another.

3. The inventions of Groups I-II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operations. The invention of Groups I-II and V are directed to either an in vitro or in vivo use, however, the invention of Groups III-IV is directed to an ex vivo use.

4. In addition to an election to one of the above groups, Applicant is required to elect:

For Group I: Applicant must elect the type of mammalian intermediary metabolite: lipid or bioconjugates. If Applicant elects bioconjugates, Applicant must elect the type: glycolipids, lipoproteins, and glycoproteins. If Applicant elects glycolipids, monosaccharade ceramide, specifically, glucosyl ceramide and galactosyl ceramide will be examined.

Lipids are structurally distinct from bioconjugates. The biological activities of these molecules are not the same. Furthermore, concerning each of the listed bioconjugates, each of these listed bioconjugates is distinct from one another. There is no significant chemical structural similarity among the bioconjugates.

For Groups I-V: Applicant must further elect the disease: cancer, an infection, or immune dysfunction. If Applicant elects an infection, Applicant must elect viral or bacterial. If Applicant elects viral, then Applicant must further elect HBV, HCV, or HIV. If Applicant elects immune dysfunction, Applicant must elect diabetes type 1, diabetes type 2, rheumatoid arthritis, Crohn's disease, arteriosclerosis, or ulcerative colitis.

Inventions directed to each of the listed type of diseases are patentably distinct from one another because the diseases are independent and distinct from one another. The activities of a bacterial disease are different from those of a viral disease. The activities of an HBV infection are different from those of HCV and HIV. The activities of cancer are different from those of an infection and immune dysfunction. The activities of an immune dysfunction disease, such as, diabetes type 1, diabetes type 2, rheumatoid arthritis, Crohn's disease, arteriosclerosis, and ulcerative colitis are different from one another.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper. The search required for Group I is not required for any of the other groups, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

E.Le

Shanon Foley
Patent Examiner, AU 1648